UNITED STATES DISTRICT COURT
DISTRICT OF DELAWARE

EURAND, INC. and ANESTA AG, Plaintiffs v. ANCHEN PHARMACEUTICALS, INC., and ANCHEN, INC., Defendants.	: : : : : : : : : : :	Honorable Judge Sue L. Robinson Civil Action No. 09-715 (SLR) **Return Date:**

OPENING BRIEF IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS OR IN THE ALTERNATIVE TO TRANSFER

MARSHALL DENNEHEY WARNER
COLEMAN & GOGGIN
Joseph Scott Shannon, Esquire (#3434)
tel.: 302.552.4329
e-mail: jsshannon@mdwcg.com
Artemio C. Aranilla, Esquire (#4516)
tel.: 302.552.4354
e-mail: acaranilla@mdwcg.com
1220 North Market Street, 5th Floor
P.O. Box 8888
Wilmington, DE 19899 – 8888

Counsel for Defendants Anchen Pharmaceuticals, Inc. and Anchen, Inc.

Of Counsel:
HUSCH BLACKWELL SANDERS
WELSH & KATZ
120 S. Riverside Plaza, 22nd Floor
Chicago, Illinois 60606
tel.: 312.655.1500
Don J. Mizerk, Esquire
Julie A. Katz, Esquire
Attorneys for Defendants Anchen Pharmaceuticals, Inc. and Anchen, Inc.

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STATEMENT OF THE NATURE AND STAGE OF THE PROCEEDINGS

Plaintiffs Eurand, Inc. and Anesta AG filed their *Complaint* (D.I. #1) on September 23, 2009, alleging Defendants Anchen Pharmaceuticals, Inc. ("Anchen Pharmaceuticals") and Anchen, Inc. (hereinafter throughout "Anchen Holding"), were infringing U.S. Patent No. 7,544,372 (the "'372 patent."). Summonses were issued and returned on September 25 and October 5, 2009, (D.I. ##7-8), after which the matter was assigned to Judge Robinson. This is the *Opening Brief in Support of Defendants' Motion to Dismiss* being filed in lieu of an answer to the complaint pursuant to Fed. R. Civ. P. 12.

This case is related to another pending case. *See Eurand, Inc. v. Anchen Pharm.*, No. 09-492 (D. Del.), also assigned to the Honorable Sue L. Robinson. Case No. 09-492, claims infringement of U.S. Patent 7,387,793 (the "'793 patent"), which is a continuation of, and the same in most material respects to the '372 patent, at issue in this case. (D.I. #1, ¶1.) Defendants have moved to dismiss that case on the same grounds, and such motion is pending. In addition, Plaintiffs contemporaneously filed additional cases identical lawsuits in California regarding the patents referenced above. *See Eurand, et al. v. Anchen Pharm.*, No. 09-cv-01098-CJC-MLG (C.D. Cal.) and *Eurand, et al. v. Anchen Pharm.*, No. 09-cv-01098-CJC-MLG (C.D. Cal.), being transferred as of October 14, 2009, to be under the same judge. Motions to dismiss those cases on the same basis asserted herein (other than lack of personal jurisdiction and improper venue) have been filed and are being filed yesterday and today.

SUMMARY OF THE ARGUMENT

1. Because Plaintiffs admit in their complaint that they have no information upon which they can allege infringement of United States Patent No. 7,544,372 (the "'372 patent"), there is no ripe "case or controversy. The Rules simply do not allow Plaintiffs to file this action to obtain discovery to determine whether they have a claim of infringement to make. Fed. R. Civ. P. 12(b)(1)

and (6); *and see, e.g., Institute for Wildlife Protection v. Norton*, 337 F. Supp. 2d 1223 (W.D. Wash. 2004).

2. Because Plaintiffs admit in their complaint that Anchen Holding did not file the ANDA application at issue, Plaintiffs cannot state a claim for patent infringement against Anchen Holding. Fed. R. Civ. P. 12(b)(6); *and see, e.g.*, *Eli Lilly & Co. v Medtronic, Inc.*, 496 U.S. 661 (1990).

3. Because Plaintiffs allege in their complaint that Anchen Pharmaceuticals only sells products in this district, Plaintiffs do not have personal jurisdiction over Anchen Pharmaceuticals. Fed. R. Civ. P. 12(b)(2); and *see Red Wing Shoe Co. v. Hockerson-Halberstadt, Inc.*, 148 F.3d 1355, 1361 (Fed. Cir. 1998).

4. Because Plaintiffs do not have personal jurisdiction over Anchen Pharmaceuticals, venue is not appropriate in this forum. Fed. R. Civ. P. 12(b)(3); and *see VE Holding Corp. v. Johnson Gas Appliance Co.*, 917 F.2d 1574, 1583-84 (Fed. Cir. 1990).

STATEMENT OF FACTS

This is a lawsuit in which Eurand, Inc. and Anesta AG (collectively "Plaintiffs") attempt to accuse Anchen Holding and Anchen Pharmaceuticals, Inc. of infringement of the '372 patent. Plaintiffs have initiated this facially deficient action, however, simply to trigger a 30-month stay of FDA approval of an application by Anchen Pharmaceuticals to market a generic version of Amrix®, a muscle relaxant.

This is a case brought under the Hatch-Waxman Amendments to the Food, Drug, and Cosmetic Act ("FDCA"), which provide an expedited review procedure for generic drug manufacturers to file for regulatory approval for generic drugs that are bioequivalent to a brand name drug. 21 U.S.C. § 355(j) (2006). Hatch-Waxman requires all New Drug Application ("NDA") holders to list all patents that are part of an NDA for a branded drug in the Approved Drug Products

with Therapeutic Equivalence Evaluations, commonly known in the industry as the "Orange Book." In addition, Hatch-Waxman allows generic pharmaceutical manufacturers to file with the Food and Drug Administration ("FDA") an Abbreviated New Drug Application ("ANDA"). Generic manufacturers need only establish that the generic drug is the bioequivalent to a referenced NDA's brand name drug. Once that standard is met and the FDA approves the ANDA, then the generic manufacture may sell its generic the day referenced patent expires.

Hatch-Waxman, however, provides for earlier entry into the market by the generic manufacturer under certain conditions. For the possibility of earlier entry into the market than the expiration of the NDA Holders patents, a generic manufacturer must do two things: (1) Certify in its ANDA that the patent in question is invalid or is not infringed by the generic product ("paragraph IV certification"); and, (2) notify the patent holder of the submission thereof. Hatch-Waxman imparts certain deadlines that are triggered at this point. For example, once the patent holder receives the ANDA notification, they have 45 days to file (if they can) a patent infringement suit against the entity, and only that entity, that filed the ANDA. If they do timely file suit, then the FDA approval of the ANDA is automatically postponed ("stayed") for 30 months or until the case is resolved in the ANDA filer's favor, whichever comes first.

In August of 2009, Anchen Pharmaceuticals, Inc. (not Anchen Holding) notified Plaintiffs that Anchen Pharmaceuticals, Inc. had amended ANDA No. 91-281 seeking FDA approval to market generic versions of Amrix®, and explaining in detail that its products, if approved by FDA, would not infringe any valid claim of the '372 patent. (*See e.g.*, D.I. #1, ¶ 24.)

From the beginning of this engagement between the parties, Defendants offered and have continued to offer Plaintiffs access to confidential information contained in the ANDA, subject to protective order-type restrictions. (*Id.,* ¶¶ 28, 30.) Plaintiffs ultimately refused Anchen

Pharmaceuticals' offer of confidential access and never accessed any information by which they could assess Anchen Pharmaceuticals' explanation, or conduct any independent assessment of their own. (*Id*., ¶¶ 28, 20, 32.)

Because they confess that they had no basis to determine if they could allege in good faith that Anchen Pharmaceuticals' generic products infringe the '793 patent, Plaintiffs filed the present action to obtain information through discovery to determine whether they have any basis to allege infringement of the '793 patent. Specifically, Plaintiffs' state in their complaint:

> 32. Plaintiffs are not aware of any other means of obtaining information regarding the Anchen Generic Products within the 45-day statutory period. In the absence of such information, Plaintiffs resort to the judicial process and the aid of discovery to obtain, under appropriate judicial safeguards, such information as is required to confirm its allegations of infringement and to present to the Court evidence that the Anchen Generic Products fall within the scope of one or more claims of the '793 and '372 Patents.

(D.I. #1, ¶ 32.)

ARGUMENT

I. UNDER THE APPROPRIATE LEGAL STANDARD, PLAINTIFFS' COMPLAINT AGAINST ANCHEN HOLDING SHOULD BE DISMISSED.

Taking all the Plaintiffs' well plead allegations as true and construing them in a light most favorable to Plaintiffs, the non-moving parties in this case, Plaintiffs' allegations do not state a legal claim upon which relief may be granted. That is the legal standard of reviewing this Motion to Dismiss under Federal Rule of Civil Procedure 12(b), and the reason for which dismissal of the *Complaint* is warranted.

A. Standard of Review

In analyzing a motion to dismiss pursuant to Rule 12(b)(6), the Court must accept as true all material allegations of the complaint and it must construe the complaint in favor of the plaintiff. *See Trump Hotels & Casino Resorts, Inc. v. Mirage Resorts, Inc.*, 140 F.3d 478, 483 (3d Cir. 1998). "A complaint should be dismissed only if, after accepting as true all of the facts alleged in the

complaint, and drawing all reasonable inferences in the plaintiff's favor, no relief could be granted under any set of facts consistent with the allegations of the complaint." *Id.*

The Court, however, need not weigh conclusory statements in its analysis, particularly those that are mere legal assumptions disguised as factual allegations. *Smith v. United States*, 113 F. Supp. 131 (D. Del. 1953) (In deciding a Rule 12(b)(6) motion, the court will not consider "conclusions of law or tenuous deductions of fact."); *Shahin v. Darling*, 606 F. Supp. 2d 525, 540 (D. Del. 2009) ("A court shall properly reject any 'conclusory recitations of law' pled within the complaint.") citing *Commonwealth of Pennsylvania v. PepsiCo, Inc.*, 836 F.2d 173, 179 (3d Cir. 1988) and *Morse v. Lower Merion School Dist.*, 132 F.3d 902, 906 (3d Cir. 1997) (noting that "a court need not credit a complaint's 'bald assertions' or 'legal conclusions' when deciding a motion to dismiss.").

B. The Court Has No Article III Subject Matter Jurisdiction Over Plaintiffs' Pursuit Of Discovery To Determine If A Claim For Patent Infringement Exists.

This is an unusual case in which the Plaintiffs admit that, because they refused Anchen Pharmaceuticals' offer of access to its confidential formulation information, they have no information about the Anchen Pharmaceuticals' ANDA products. (D.I. #1, ¶¶ 28, 20, 32.) Thus, Plaintiffs must concede that they have no basis upon which to even allege that the Anchen Pharmaceuticals ANDA products infringe '372 patent. *Id.* Because Plaintiffs acknowledge that they are unable to state a claim of infringement based upon the information they possess, their case is not yet ripe and there is no justiciable case or controversy. Plaintiffs improperly filed this action to obtain discovery from which they can determine whether they have a Federal Rule of Civil Procedure 11 ("Rule 11") basis to allege infringement relating to the Anchen Pharmaceuticals ANDA product. In their complaint, Plaintiffs state:

> 32. Plaintiffs are not aware of any other means of obtaining information regarding the Anchen Generic Products within the 45-

> day statutory period. In absence of such information, Plaintiffs resort to the judicial process and the aid of discovery to obtain, under appropriate judicial safeguards, such information as is required to confirm its allegations of infringement and to present the Court evidence that the Anchen Generic Products fall within the scope of one or more claims of the '793 and '372 Patents.

(D.I. #1, ¶ 32; *see also* ¶10 (stating need for discovery to make a jurisdictional allegation).)

The filing of a complaint for the purpose of taking discovery in order to determine whether a claim exists, or not, is improper on its face and will result in dismissal of the action in the lack of any competent facts supporting the plaintiff's averments. *E.g.*, *Telcordia Techs., Inc. v. Alcatel S.A.*, 2005 U.S. Dist. LEXIS 10194 (D. Del. May 27, 2005) ((“a plaintiff may not rely on the bare allegations in his complaint to warrant further discovery” and “the court must be satisfied that there is some indication that this particular defendant is amenable to suit in this forum”) (internal citations omitted)).

The Federal Rules simply do not permit Plaintiffs to initiate a case to determine whether they have one. “To maintain an action in federal court, an *actual* case or controversy must exist, and discovery may not be used to conduct a fishing expedition in hopes that some fact supporting an allegation will be uncovered.” *Institute for Wildlife Protection v. Norton*, 337 F. Supp. 2d 1223, 1226 (W.D. Wash. 2004) (emphasis added). “[T]he purpose of discovery is to distill the issues in a case for trial, not to gather information to support a complaint.” *Decatur Ventures, LLC v. Stapleton Ventures, Inc.*, 373 F. Supp. 2d 829, 843 (S.D. Ind. 2005).

The Federal Rules allow for pre-suit discovery in only very limited circumstances and Plaintiffs do not allege that this is one of them – nor could they. Federal Rule of Civil Procedure 27 (“Rule 27”) addresses the limited availability of pre-suit discovery. “The Court of Appeals for the Third Circuit has decisively rejected the attempt to use Rule 27(a) as a mechanism to draft a complaint or conduct pre-trial discovery.” *In re Chester County Elec. Inc.*, 208 F.R.D. 545, 547

(E.D. Pa. 2002). *See e.g.*, *In re I-35W Bridge Collapse Site Inspection*, 243 F.R.D. 349, 352 (D. Minn. 2007) ("Rule 27 does not provide 'a method of discovery to determine whether a cause of action exists; and, if so, against whom the action should be initiated.'") (*citing In re Gurnsey*, 223 F. Supp. 359, 360 (D.D.C. 1963) (other internal citations omitted); *Lucas v. Judge Advocate General*, 245 F.R.D 8, 9 (D.D.C. 2007) (other internal citations omitted); *In re Ramirez*, 241 F.R.D. 595, 596 (W.D. Tex. 2006) ("In other words, Rule 27 may not be used as a vehicle for discovery prior to filing a complaint."); *In re Landry-Bell*, 232 F.R.D. 266, 267 (W.D. La. 2005) ("Rule 27 does not allow for pre-suit discovery in order to determine compliance with Rule 11…. The overwhelming weight of authority simply does not authorize the use of Rule 27 to conduct the type of pre-suit discovery Petitioner requests herein."); *In re Chester County Elec. Inc.*, 208 F.R.D. 545, 547-48 (E.D. Pa. 2002) ("The motion was denied because the testimony was sought to draft a complaint, not perpetuate testimony, and if granted would have been an abuse of the Rule."); *In re Strorck*, 179 F.R.D. 57, 58 (D. Mass. 1998) ("The rule is not designed to allow pre-suit discovery."); *In re Sitter*, 167 F.R.D. 80, 82 (D. Minn. 1996) ("[T]he relevant case law does not allow the deployment of Rule 27 so as to conduct pre-Complaint discovery."); *In re Ford,* 170 F.R.D. 504, 508 (M.D. Ala. 1997) ("The problem is that Rule 27 is not a vehicle for compliance with Rule 11. As stated, the language in Rule 27 is clear that the Rule authorizes the perpetuation of evidence, not the discovery or uncovering of it."). Plaintiffs cannot legitimately attempt to obtain through Rule 26, what they are explicitly denied under Rule 27.

Plaintiffs contend that they only had 45 days to obtain the information they needed to evaluate their case, and filed the case because they were unable to obtain such information within that timeframe. (Complaint, ¶ 32.) Plaintiffs' assertion, however, of some sort of "Catch 22" is simply of no avail. No case or controversy exists until Plaintiffs state a proper basis to allege

infringement. *See e.g.*, *In re Ford*, 170 F.R.D. 504, 509 (M.D. Ala. 1997) ("However, without the discovery incident to litigation, Ford is without the means to uncover whether her father was a victim of foul play in violation of a clearly established federal right. Her predicament is a 'Catch 22.' … the court has no answer for her, however, other than that Rule 27 does not offer an avenue of relief.").

Because Plaintiffs admit that they have no information upon which to base any allegation of infringement and have filed this action as a direct means of obtaining discovery to determine whether they have such a claim, there is no ripe "case or controversy", there is no subject matter jurisdiction, and their complaint fails to state a claim upon which relief can be granted. Thus, 12(b)(1) and (6) require the dismissal of Plaintiffs' complaint.

C. Plaintiffs Fail To State A Claim For Patent Infringement Against Anchen Holding.

Plaintiffs admit that Anchen Holding did not file the ANDA at issue. (Complaint, ¶ 23, 24) Only Anchen Pharmaceuticals, Inc. sent Plaintiffs a certification or notice letter advising them of the ANDA filing. Plaintiffs admit that Anchen Holding is a separate legal entity from Anchen Pharmaceuticals, Inc. (*Id.,* ¶¶ 4, 5, 23, 24.) Thus, Plaintiffs have not stated any reasoned basis to state a claim for patent infringement against Anchen Holding.[1]

First, Count I of Plaintiffs' complaint against Anchen Holding must be dismissed because Plaintiffs admit that Anchen Pharmaceuticals, Inc., not Anchen Holding, submitted the ANDA at

[1] In another case involving the '793 patent, Plaintiffs similarly attempted to add the ANDA filer's parent corporation to the complaint as a named defendant. The parent corporation filed a motion to dismiss based on the same arguments presented here. Plaintiffs did not even respond to the motion, but stipulated to the dismissal of the parent corporation, thus mooting the motion. *See Eurand, Inc.* et al. *v. Mylan Pharmaceuticals, Inc.*, Civil Action No. 08-00889 (SLR) (D. Del.) (D.I. #18 and 42). Moreover, Defendants' counsel attempted to resolve this issue voluntarily with Plaintiffs' counsel given that the inclusion of Anchen, Inc. provides no additional protection or relief to Plaintiffs in this case. In another recent case, plaintiffs have agreed to dismiss Anchen, Inc. without prejudice and avoid such motion practice in that case. *See Eli Lilly & Co. v. Anchen Pharmaceuticals, Inc.*, No. 09-CV-1029-WTL-JMS (S.D. Ind.) (D.I. #12).

issue to FDA. (*Id.,* ¶ 34.) As such, Plaintiffs claims of direct infringement against Anchen Holding fail as a matter of law.

35 U.S.C. § 271(e)(2)(A) provides that: It shall be an act of infringement to submit - (A) an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in section 505(b)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent…. Under 35 U.S.C. § 271(e)(2), the "highly artificial" act of patent infringement occurs by the entity submitting the ANDA that challenges the validity and enforceability of Eurand's patent. *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678, 679 (1990). Writing for the United States Supreme Court, Justice Scalia stated that:

> [A]n act of infringement had to be created for these ANDA and paper NDA proceedings. That is what is achieved by 271(e)(2) - the creation of a highly artificial act of infringement that consists of submitting an ANDA or a paper NDA containing the fourth type of certification that is in error as to whether commercial manufacture, use, or sale of the new drug (none of which, of course, has actually occurred) violates the relevant patent.

Id. As such, only the entity that submits this information to the FDA – and no other entity – can have committed the technical act of patent infringement under the statute. *SmithKline Beecham Corp. v. Geneva Pharms., Inc.*, 287 F. Supp. 2d 576, 584 (E.D. Pa. 2002) ("By its terms, the Act limits liability for direct infringement to the party submitting the ANDA."); *SmithKline Beecham Corp. v. Pentech Pharms., Inc.*, 2001 WL 184804, at *2 (N.D. Ill. Feb. 20, 2001) ("The plain language of the statute controls …. Section 271(e)(2)(A) unambiguously refers only to persons who submit the ANDA.). Thus, because Plaintiffs admit that Anchen Holding did not submit the ANDA, they have failed to state a claim for direct patent infringement against Anchen Holding.

Second, Count II of Plaintiffs' complaint contends that Anchen Holding "induced" Anchen Pharmaceuticals, Inc. to submit the ANDA at issue. (D.I. #1, ¶ 38.) "Inducing" the filing of an

ANDA fails to state a claim for patent infringement. *See Pfizer Inc. v. Ranbaxy Labs, Ltd.*, 321 F. Supp. 2d 612, 616 (D. Del. 2004)("[A] claim for inducement of infringement cannot be based solely upon allegations that a defendant aided and abetted the filing of an ANDA."); *Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc.,* 267 F. Supp. 2d 545, 548-49 (N.D. W. Va. 2003) (dismissing claims for inducement of filing an ANDA); *AstraZeneca AB v. Mylan Labs.*, *Inc.,* 265 F. Supp. 2d 213, 217 (S.D.N.Y. 2003)("[W]hether the submission of an ANDA was induced is not the proper subject of a Hatch-Waxman action.").

The reasoning underlying these correct district court decisions is that in a Hatch-Waxman action, the issue is the technical or artificial patent infringement based on the ANDA product rather than on the ANDA filing or the decisions leading to the ANDA filing. *AstraZeneca*, 265 F. Supp. 2d at 217 ("[T]he inquiry is properly focused on the ANDA product, not the ANDA filing."); *Pfizer*, 321 F. Supp. 2d at 616-17; *Ortho-McNeil*, 267 F. Supp. 2d at 548-49.

Finally, Count III of Plaintiffs' complaint is merely a traditional request for a declaration of infringement – directly, indirectly or contributorily – against Anchen Holding. (Complaint, ¶ 42). This count, however, fails to state a claim in light of Plaintiffs admissions that Anchen Pharmaceuticals filed the ANDA (*Id.,* ¶ 23, 24), that Anchen Pharmaceuticals is the entity that conducts business in the United States (*Id.*, ¶ 7), and that Anchen Holding and Anchen Pharmaceuticals are "separate entities" (*Id.*, ¶¶ 4, 5). Having admitted all the central facts, Plaintiffs cannot leap over them and create liability for patent infringement with mere statements of "joint action" or with allegations of wishful legal conclusions. *See Morse*, 132 F.3d at 906 (3d Cir. 1997) ("[A] court need not credit a complaint's 'bald assertions' or 'legal conclusions' when deciding a motion to dismiss.").[2]

[2] This is not a trademark infringement action. Therefore, any purported statements made in 2007 during the prosecution of a pending trademark application concerning the ownership of the ANCHEN *trademark* have no

For the reasons set forth above, Count III of Plaintiffs' complaint fails to state a claim against Anchen Holding.

II. PLAINTIFFS FAIL TO ARTICULATE WITH REASONABLE PARTICULARITY FACTS THAT SUGGEST THE EXISTENCE OF PERSONAL JURISDICTION OVER ANCHEN PHARMACEUTICALS.

A. Plaintiffs Fail To Meet Their Burden To Show That Personal Jurisdiction Over Anchen Pharmaceuticals Is Proper In Delaware.

Plaintiffs' fail to meet their burden to show that personal jurisdiction over Anchen Pharmaceuticals is proper in Delaware. In a patent infringement action, the law of the Court of Appeals for the Federal Circuit governs. *Liveperson, Inc. v. Nextcard, LLC*, 2009 U.S. Dist. LEXIS 22902 (D. Del. Mar. 20, 2009), citing *Breckenridge Pharm., Inc. v. Metabolite Labs.*, Inc., 444 F.3d 1356, 1361 (Fed. Cir. 2006). Under Federal Circuit law, personal jurisdiction can be established if the defendant is subject to personal jurisdiction in Delaware under Delaware's long-arm statue. In this regard, under Delaware's long-arm statue, the Court looks at whether the defendant has sufficient minimum contacts with the state to meet statutory ("'extensive and continuing' contacts") and constitutional requirements. *LG Elecs., Inc. v. ASKO Appliances, Inc.*, 2009 U.S. Dist. LEXIS 53391, at *10 (D. Del. June 23, 2009) (Incorporation in a state does not even support personal jurisdiction in that state when the company is "merely a passive holding company that engages in no production activities."); *Physician Endorsed LLC v. Clark*, 374 F. Supp. 2d 395, 397-98 (D. Del. 2005).

Personal jurisdiction sufficient to meet due process requirements can be established either "generally" or "specifically." General jurisdiction can be defined as the court's exercise of personal jurisdiction over a defendant based upon that entity's contacts with the forum that are unrelated to the cause of action plead by the plaintiff.

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bearing on the filing of an ANDA in 2009. (D.I. #1, ¶ 6.)

To establish general jurisdiction in this jurisdiction, defendant's contacts with the state must be continuous and systematic. *See e.g., Silent Drive, Inc. v. Strong Indus, Inc.*, 326 F.3d 1194, 1220 (Fed Cir. 2003); *Merck & Co. v. Barr Labs., Inc.*, 179 F. Supp. 2d 368, 371 (D. Del. 2002); *Osteotech, Inc. v. Gensci Regeneration Scis., Inc.*, 6 F. Supp. 2d 349, 353 (D.N.J. 1998) (noting that burden of showing such contacts is "rigorous") (citation omitted). For example, to support general jurisdiction, Plaintiffs must show that Anchen regularly transacts or solicits business within the state, or maintains an office or agents there. *Physicians Endorsed LLC v Clark*, 374 F. Supp. 2d 395, 398 (D. Del. 2005) ; *Helicopteros Nacionales v. Hall*, 466 U.S. 408, 414-16 (1984). The exercise of general personal jurisdiction over a non-resident entity presents a difficult burden and is often rejected as a basis for the exercise of jurisdiction by courts. See Id. (denying general jurisdiction over a corporate defendant who had purchased millions of dollars of goods, negotiated contracts and trained employees in the forum state).

Specific jurisdiction over a defendant arises from the defendant's contacts with the state relate to the "specific" cause of action at issue. In analyzing specific jurisdiction, the Federal Circuit considers "whether (1) the defendant purposefully directed its activities at the residents of the forum state, (2) the claim arises out of or relates to the defendant's activities within the forum state, and (3) assertion of personal jurisdiction is reasonable and fair." *Pennington Seed, Inc. v. Product Exch. No. 299*, 457 F3d 1334, 1344 (Fed. Cir. 2006) (citation omitted); *HollyAnne Corp. v. TFT, Inc.*, 199 F.3d 1304, 1307 (Fed. Cir. 1999).

The "highly artificial" act of patent infringement occurs by Anchen Pharmaceuticals submitting the ANDA to the FDA that challenges the validity and enforceability of Eurand's patent. 35 U.S.C. § 271(e)(2); *Eli Lilly*, 496 U.S. at 678, 679 (1990). Once a defendant challenges jurisdiction, the burden is on the plaintiff to prove facts with reasonable particularity sufficient to

establish personal jurisdiction. *Provident Nat'l Bank v. California Fed. Sav. & Loan Assoc.*, 819 F.2d 434, 437 (3d Cir. 1987). "While at this stage, the Court will consider all allegations of jurisdictional facts in a light most favorable to the assertion of personal jurisdiction, conclusory jurisdictional statements will not suffice." *Richard v. Bell Atlantic Corp.*, 946 F. Supp. 54, 67 (D.D.C. 1996). Plaintiffs cannot meet their burden simply by parroting the various jurisdictional standards in a conclusory manner. Here, Plaintiffs' jurisdiction allegations are as follows:

> 9. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a), 35 U.S.C. § 271, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02.
>
> 10. Based on the facts and causes alleged herein, and for additional reasons to be further developed through discovery, this Court has personal jurisdiction over the Anchen Defendants.
>
> 11. On information and belief, this court has personal jurisdiction over Anchen Pharmaceuticals, Inc. by virtue of its systematic and continuous contacts with the State of Delaware.
>
> 12. On information and belief, Anchen Pharmaceuticals, Inc. plans to continue to maintain continuous and systematic contacts with the State of Delaware, including but not limited to, its aforementioned business of preparing generic pharmaceuticals that it distributes in the State of Delaware.
>
> 13. This Court has personal jurisdiction over Anchen, Inc. by virtue, inter alia, of its incorporation in Delaware.
>
> 14. Venue is proper in this District under 28 U.S.C. §§ 1391 and 1400(b).

(D.I. #1, ¶¶ 9-14, emphasis added.) These jurisdictional allegations are woefully insufficient, however, to establish personal jurisdiction over Anchen Pharmaceuticals.

The specific facts that Plaintiffs have plead, even if true, are not sufficient to establish personal jurisdiction over Anchen Pharmaceuticals. In this case, Plaintiff Eurand (the patent holder of the '793 patent) is a Nevada corporation located in Ohio (D.I. #1, ¶ 2); Plaintiff Anesta (the exclusive licensee of the '793 patent) is a Swiss company, located in Switzerland (D.I. #1, ¶ 3);

Defendant Anchen Pharmaceuticals is a California corporation located in California (D.I. #1, ¶ 4); the ANDA at issue was filed with the FDA in Maryland (D.I. #1, ¶ 23); Anchen Pharmaceuticals' required notice letter was sent to Eurand and Anesta via Ohio where Eurand is actually located. (D.I. #1, ¶¶ 2, 23). The only contact with Delaware is that Anchen Holding is incorporated here. None of the primary interactions between the parties take place in Delaware, including the technical act of infringement in this case, which is the ANDA filing and required notice letter. These contacts with Delaware are not sufficient to establish personal jurisdiction as a matter of law when even a defendant's ANDA filing is not enough to confer specific jurisdiction upon courts in the patent holder's home state – and Delaware is not even the patent holder's home state in this case. *Abbott Labs. v. Mylan Pharms., Inc.*, No. 05 C 6561, 2006 U.S. Dist. LEXIS 13782, at *7-8 (N.D. Ill. Mar. 28, 2006).

For example, in *Abbott Labs*, the Plaintiff patent holder was a company headquartered in Chicago, Illinois. It sued the West-Virginia-based defendant in the Northern District of Illinois after the defendant filed an ANDA that allegedly infringed the plaintiff's patent. The Court recognized that the filing did not give rise to specific jurisdiction: "No part of the preparation of the ANDA or the filing the ANDA took place in Illinois, and there has been no other injury to [defendant], so there is no basis for asserting specific jurisdiction over [the defendant]." Id. Similarly, the Federal Circuit held in HollyAnne that it is not enough that the patent holder in an infringement action resides in the forum state. Instead, the plaintiff must show that the defendant actually took some action in the state. 199 F.3d at 1308. There, the defendant, a California corporation, sold items infringing on the Nebraska plaintiff's patent. *Id.*, at 1305. The focus was on whether the defendant's alleged infringement caused "harm…felt by" the plaintiff in the State of Nebraska. However, none of the sales of the allegedly infringing items occurred in Nebraska, and the Court

held that District Court for the District of Nebraska did not have personal jurisdiction over the California defendant. Id., at 1308-09. The Court came to this conclusion despite that one of the defendant's officers had given a presentation in the State of Nevada. Id. Applying this logic to the present situation, Anchen Pharmaceuticals is a California based company that filed an ANDA with the FDA's Maryland office. Here, not even the patentee resides in this state. This is the highly artificial act of infringement in no way involved Delaware.

B. The Few Delaware Contacts Plaintiffs Allege, Even If Proven, Would Be Insufficient To Establish General Jurisdiction Over Anchen Pharmaceuticals In Delaware.

Even assuming arguendo that Plaintiffs can eventually prove the truth of every jurisdictional allegation they made, those "facts" would nonetheless be insufficient to confer general jurisdiction over Anchen Pharmaceuticals. Plaintiffs have pled merely that Anchen Pharmaceuticals "distributes [generic pharmaceuticals] in the State of Delaware and throughout the United States." (D.I. #1, ¶ 7). Plaintiffs also summarily allege that Anchen "has sold millions of dollars worth of Bupropion and Divalproex pharmaceutical products within the United States generally, and the State of Delaware specifically." (D.I. #1, ¶ 7). Selling generic pharmaceutical products to distributors who then in turn sell to consumers in Delaware is far from the kinds of contacts that will confer general jurisdiction over Anchen Pharmaceuticals. These activities certainly fall far short of establishing the kind of substantial and continuous contacts with Delaware that are necessary to create general jurisdiction over Anchen Pharmaceuticals.

(1) Even If Delaware Residents Bought Anchen Pharmaceuticals' Generic Pharmaceutical Products, That Does Not Support General Jurisdiction Over Anchen Pharmaceuticals.

Plaintiffs' allegations of Anchen Pharmaceuticals selling millions of dollars worth of generic pharmaceuticals throughout the United States, including Delaware is insufficient to establish general personal jurisdiction over Anchen Pharmaceuticals in this state. Plaintiffs make no

claim that Anchen Pharmaceuticals' sales of unrelated pharmaceutical products came disproportionately from Delaware. Plaintiffs make no claim that Anchen Pharmaceuticals targeted Delaware consumers or that Delaware was any different than any other state with regard to Anchen Pharmaceuticals' general business activities. *See Gehling v. St. George's School of Medicine, Ltd.*, 773 F.2d 539, 541, 543 (3rd Cir. 1985) (Having purposeful contact with a state does not necessarily constitute continuous and substantial business for the purpose of conferring personal jurisdiction.).

Even the allegation that "Anchen has sold millions of dollars worth" of other products in the United States with some of those sales to Delaware is insufficient to establish general jurisdiction over Anchen Pharmaceuticals. The Federal Circuit specifically declined to hold that merely receiving sales revenue from a state is enough, by itself, to support general jurisdiction. *See Delta Sys. v. Indak Mfg. Corp.*, 4 Fed. Appx. 857, 860 (Fed. Cir. 2001) (stating only that millions of dollars of sales from a "substantial contingent" of forum-state buyers might be sufficient to support jurisdiction); *see also Gehling*, 773 F.2d at 541-43 (general jurisdiction not conferred over a defendant school having advertised in nationals newspapers that had substantial circulation in Pennsylvania, received approximately six percent of its students from Pennsylvania, staged a media campaign that included appearances on Philadelphia radio and television shows, and entered into a long-term arrangement with a school in Pennsylvania); *XL Specialty Ins. Co. v. Melexis GmbH*, 2007 U.S. Dist. LEXIS 76672 (D.N.J. Oct. 16, 2007) (allegation that defendant sold goods in New Jersey through a representative was "too insubstantial to serve as the basis for this Court's general jurisdiction over [defendant]"); *In re Wexco*, 2006 U.S. Dist. LEXIS 57411 (D. N.J. Aug. 14, 2006) (holding that the fact that defendant's product was eventually bought in New Jersey did not create general jurisdiction).

For the Court to accept Plaintiffs' jurisdictional approach would effectively hold that any corporation with national sales is subject to general jurisdiction in every state. The Court should not be willing to take that kind of step. *Molnlycke Health Care AB v. Dumex Medicalsurgical Products Ltd.*, 64 F. Supp. 2d 448, 451 (E.D. Pa. 1999). The Third Circuit and its district courts have typically required a very high showing before exercising general jurisdiction." *Id.*; *see In re Wexco*, 2006 U.S. Dist. LEXIS 57411 at *17 n.2 ("To allow for personal jurisdiction in these circumstances would open the floodgates for manufacturers to be liable for their actions in any forum that their product may end up, even if a plaintiff's cause of action does not relate to the product. If permitted, litigants could bring suit against large manufacturers in virtually every state. Allowing such an expansive interpretation of personal jurisdiction is not supported by common sense or case law."). Consequently, with no personal jurisdiction over Anchen Pharmaceuticals in Delaware based on Fed. R. Civ. P. 12(b)(2), the instant Motion to Dismiss is justified.

C. Venue Is Improper In Delaware.

The lack of personal jurisdiction over Anchen Pharmaceuticals makes venue improper in Delaware. In a patent infringement action, venue is proper in any judicial district "where the defendant resides or where the defendant has committed acts of infringement and has a regular and established place of business." 28 U.S.C. § 1400(b). A corporation is "deemed to reside in any judicial district in which it is subject to personal jurisdiction at the time the action is commenced." 28 U.S.C. § 1391(c). Because venue is proper only where personal jurisdiction is proper, the two analyses are the same. *VE Holding Corp. v. Johnson Gas Appliance Co.*, 917 F.2d 1574, 1583-84 (Fed. Cir. 1990). Because the Court lacks personal jurisdiction over Anchen Pharmaceuticals, venue in the District of Delaware is not proper. Fed. R. Civ. P. 12(b)(3).

III. ALTERNATIVELY, THIS CASE SHOULD BE TRANSFERRED TO THE CENTRAL DISTRICT OF CALIFORNIA.

Should the Court determine that it possesses subject matter and personal jurisdiction over Defendant(s), this case should nevertheless be transferred to the Central District of California pursuant to 28 U.S.C. § 1404(a) ("Section 1404(a)"). This case has no connection (substantial or otherwise) with the State of Delaware and, if allowed to proceed, should be transferred to a venue that is more convenient for the litigants, the Central District of California.

Venue is clearly proper in the Central District of California because that is where the Defendants' principal places of business are located. (Complaint, ¶¶ 4, 5.) Moreover, Plaintiffs have selected this jurisdiction as their "second choice" for this litigation and have already filed identical cases in that district against Defendants. *See Eurand v. Anchen Pharma.*, No. 09-cv-04931 CBM-MLG (C.D. Cal.) (regarding '793 patent) and *Eurand v. Anchen Pharma*, No. 09-cv-01098-CJM-MLG) (C.D. Cal.) (regarding '372 patent).

Under Section 1404(a), transfer motions are determined by considering the convenience factors and what is in the interests of justice. *See Micron Tech., Inc. v. MOSAID Techs., Inc.,* 518 F.3d 897, 904-05 (Fed.Cir.2008) (allowing effective consolidation of two actions involving some overlapping patents and defendants and noting that first-filed rule should not be automatically applied because "the trial court weighing jurisdiction additionally must consider the real underlying dispute: the convenience and suitability of competing forums"); *see also Jumara v. State Farm Ins. Co.,* 55 F.3d 873, 879-80 (3d Cir.1995) (listing twelve non-exclusive factors to consider when evaluating motion to transfer, including the three enumerated in the statute: convenience of parties, convenience of witnesses, or interests of justice).

Under *Jumara,* the Court looks at factors such as the private interest of not overturning a plaintiff's forum preference. But this factor is not an issue because Plaintiffs selected *both* venues

– Plaintiffs chose the California venue in a contemporaneously filed action. All of the Anchen documents and witnesses are located in California. *Jumara,* 55 F.3d at 879-80. There are no discernable connections or conveniences for any party by having the litigation proceed in Delaware.

Moreover, it appears that Plaintiffs have added gratuitous parties in an effort to manufacture the appearance of some connection to Delaware by initially including Cephalon as a plaintiff (and subsequently dismissing it from the case) and Anchen, Inc. as a defendant. It cannot be in the interests of justice to permit Plaintiffs to manipulate the facts affecting venue determinations in this manner. Keeping the case in Delaware is simply an odd result given the location of the parties, the situs of the original ANDA filing, and the ultimate relief sought from the complaint.

CONCLUSION

WHEREFORE, for the reasons stated hereinabove, Defendants request this Honorable Court for an Order dismissing Plaintiffs' *Complaint* against Defendants as to all counts and claims, or in the alternative transfer to the Central District of California, with an award of Defendants' attorneys' fees and costs incurred in defending this action and bringing this *Motion for Dismissal or Transfer*, and such other relief as the Court finds appropriate, mete and just.

MARSHALL DENNEHEY WARNER
COLEMAN & GOGGIN
By: /s/ J. Scott Shannon
Joseph Scott Shannon, Esquire (#3434)
tel.: 302.552.4329
e-mail: jsshannon@mdwcg.com
Artemio C. Aranilla, Esquire (#4516)
tel.: 302.552.4354
e-mail: acaranilla@mdwcg.com
1220 North Market Street, 5th Floor
P.O. Box 8888
Wilmington, DE 19899 – 8888

Counsel for Defendants Anchen Pharmaceuticals, Inc. and Anchen, Inc.

Of Counsel:
HUSCH BLACKWELL SANDERS
WELSH & KATZ
120 S. Riverside Plaza, 22nd Floor
Chicago, Illinois 60606
tel.: 312.655.1500
Don J. Mizerk, Esquire
Julie A. Katz, Esquire

Attorneys for Defendants Anchen Pharmaceuticals, Inc. and Anchen, Inc.

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